SUMMARY OF THE QUALITY SYSTEMS COMMITTEE MEETING JANUARY 5, 1999

The Quality Systems (QS) Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met by teleconference on January 5, 1999, at 10 a.m. Eastern Standard Time (EST). The meeting was led by its chair, Mr. Joe Slayton of the U.S. Environmental Protection Agency's (EPA) Region III. A list of action items is given in Attachment A. A list of participants is given in Attachment B. A list of parking lot issues is given in Attachment C. QS Committee participant draft responses to comments from the Virginia NELAC Workgroup are presented in Attachment D. *The purpose of the meeting was to: (1) review action items from the previous meeting, (2) address parking lot and administrative issues, (3) discuss the Virginia NELAC Workgroup comments, and (4) discuss the agenda for the NELAC Interim Meeting.*

REVIEW OF ACTION ITEMS FROM PREVIOUS MEETINGS

All of the action items listed in the minutes of the December 7, 1998 meeting were addressed except for the following:

- The QS Committee still needs to review the language Mr. Porterfield drafted for Section 5.10.2.1, Initial Demonstration of Capability (IDOC).
- QS Committee participants drafted responses to the comments received from the Virginia NELAC Workgroup. These responses will be sent by Mr. Slayton to Dr. Kenneth Jackson. (The discussion of these responses was begun during this teleconference and is listed below.)
- To eliminate the reference to *3.18 times the MDL*, Section 5.13.a.17 was changed to read as follows: *clear identification of numerical results with values ~~below 3.18 times the MDL (10 standard deviation as determined by the method detection limit study~~ outside the quantitation limits.*

DISCUSSION OF PARKING LOT ITEMS FROM DECEMBER 7, 1998

Item 2: It was mentioned that during the NELAC Board of Directors meeting a proposal was made that if standards are different, without one being more stringent than the other, then both standards should be required. The comment was made that if this is the case then the two standards may be similar enough that requiring both would not be necessary.
It was pointed out that the key issue is differences that may exist between a requirement for an analytical method and a requirement in Chapter 5 as opposed to differences between the requirements of two separate analytical methods. All members are to provide examples of this issue (methods vs. QS requirements). If examples cannot be provided/ found, this will be dropped as an issue.

Item 3: Chapter 5 has been searched for references to *MDL* and *3.18* and the necessary changes made to the language.

Item 6: The homework items for the NELAC IV Conference still need to be discussed. Mr. Slayton will redistribute the list of items for discussion at the NELAC Interim Meeting.

DISCUSSION OF ADMINISTRATIVE ISSUES

It was pointed out that the table of contents for Chapter 5 should be regenerated with each new version of the chapter.

The question was raised as to what materials should be routinely included as attachments to the minutes. It was decided that, in addition to action items and the list of participants, only the updated list of parking lot items/issues should be routinely attached to the minutes. However, the minutes should capture any proposed changes to the language of Chapter 5.

If possible, the letter acknowledging receipt of comments, the format template for submitting comments, and the QS Committee's standards review criteria should be made available on the NELAC Website as separate items from the minutes. Otherwise, commenters should be directed to the December 7, 1998 teleconference minutes to obtain copies of these items.

Additional comments have also been received by Mr. Slayton from Mr. Robert Green of Alcoa and Ms. Jenny Scifres of EPA Region IV. Mr. Slayton will draft responses to both comments.

DISCUSSION OF RESPONSES TO VIRGINIA NELAC WORKGROUP COMMENTS

Responsibility for drafting responses to comments from the Virginia NELAC Workgroup was divided among the QS Committee participants. Only the proposed responses that involved changes to the language of Chapter 5 were discussed by the entire committee. However, all responses to comments are documented. For a detailed discussion of the comment and response, refer to Attachment D.

Comments Assigned to Mr. Slayton: One comment pointed out that the term *client* can have many meanings and it was decided that the definition of client needs further exploration. It was also pointed out that within a quality system, a client can be internal or external to an organization.

Comments Assigned to Mr. Mendenhall: After reviewing the proposed changes, the committee felt that none of the comments required changes to the existing language of Chapter 5.

Comments Assigned to Ms. Bruch: None of the comments required changes to the existing language of Chapter 5.

Comments Assigned to Mr. Frederici: To address the comment regarding Section 5.6.2.c.3, the text in 5.6.2.3.ii was changed as follows: *Another initial demonstration of method ~~performance~~ capability*.

Mr. Slayton will send Mr. Jackson the responses drafted by the QS Committee participants and will indicate which ones have been discussed by the entire committee.

Parking Lot Items/Issues number 1, 4, 5, 7, 8, and 9 still need to be addressed.

Attachment A

ACTION ITEMS
QUALITY SYSTEMS COMMITTEE
JANUARY 5, 1999

Item No.	Action Item	Date to be Completed
1.	QS Committee to review Initial Demonstration of Capability and language drafted by Mr. Porterfield for Section 5.10.2.1.a.3.	At NELAC Interim Meeting
3.	Add Mr. Slayton's full citations for the references in Section 5.9.4 to the reference section of Chapter 5, Appendix A.	
4.	Mr. Cross to look into posting the acknowledgment letter, commenter template, and the QS Committee's review criteria separate from the meeting minutes.	
5.	Mr. Slayton to draft response to Mr. Green's comment on Chapter 5.	
6.	Mr. Slayton to send acknowledgment letter to Ms. Scifres and draft a response to her comment on Chapter 5.	
7.	Mr. Slayton to send Mr. Jackson the responses to the comments from the Virginia NELAC Workgroup that the QS Committee participants drafted.	
8.	Mr. Slayton to redistribute list of homework items from the NELAC IV Conference.	Prior to the NELAC Interim Meeting
9.	All participants to provide examples concerning item #2 (from parking lot discussion-first page of these minutes)	
10.	Slayton/Cross to update 9.07 version of the chapter to reflect proposed changes from 1/5/99.	After the Interim Meeting (NELAC IVi).

Attachment B

PARTICIPANTS
QUALITY SYSTEMS COMMITTEE
JANUARY 5, 1998

Name	Affiliation	Phone Numbers
Mr. Joe Slayton	USEPA, Region III, OASQA	T: 410-573-2653 F: 410-573-2698 E: slayton.joe@epamail.epa.gov
Ms. Mary K. Bruch	Mary Bruch Micro Reg. Inc.	T: 703- 589-1514 F: 703- 779-0267 E:
Mr. Raymond J. Frederici	Recra Labnet - Chicago	T: 708-534-5200 F: 708-534-5211 E: frederir@recra.com
Mr. Clifford R. Glowacki	Ashland Chemical Company	T: 614-790-3482 F: 614-790-4294 E: cglowacki@ashland.com
Ms. Sylvia S. Labie	Florida Department of Environmental Protection	T: 904-488-2796 F: 904-922-4614 E: labie_s@dep.state.fl.us
Mr. David Mendenhall (Absent)	Utah Department of Health	T: 801-584-8470 F: 801-584-8501 E: dmendenh@doh.state.ut.us
Ms. Sheila Meyers	Texas Natural Resource Conservation Commission	T: 512-239-0425 F: 512-239-6307 E: smeyers@tnrcc.state.tx.us
Mr. Jeff Nielson	City of Tallahassee Water Quality Division	T: 850-891-1232 F: 850-891-1062 E: nielsenj@mail.ci.tlh.fl.us
Mr. Donivan R. Porterfield	Los Alamos National Laboratory	T: 505-667-4710 F: 505-665-5982 E: dporterfield@lani.gov
Mr. Scott D. Siders	Illinois Environmental Protection Agency	T: 217-785-5163 F: 217-524-0944 E: epa6113@epa.state.il.us
Dr. Fred Siegelman	US EPA, QAD	T: 202-564-5173 F: 202-564-2441 E: siegelman.frederic@epamail.epa.gov
Mr. Mike Cross (Contractor Support)	Research Triangle Institute	T: 202-728-2045 F: 202-728-2095 E: myc@rti.org

Attachment C

PARKING LOT ITEMS/ISSUES
QUALITY SYSTEMS COMMITTEE
JANUARY 5, 1999

Parking Lot Items/Issues as of December 7, 1998. Items/issues will remain in the Parking Lot until they are completed.

1. Air Appendix

The Air Analysis Workgroup has a number of editorial changes which were deferred from the November 8-10, 1998 QS Committee meeting because of lack of time. These items will be discussed at that time.

2. Proposed New Appendix

Appendix for listing of required records (all pulled into one table). Need to reach consensus on the table and the suggested introduction provided by Mr. Porterfield.

3. Continuous Monitors

This topic was briefly discussed at the Annapolis meeting (11/10/98) and it was decided that this topic may require its own appendix with associated special quality control (QC).

4. Action Items from the NELAC IV Conference.

This was a homework item and most of the work is completed but it has not been discussed.

5. Initial Demonstration of Capability (IDOC)

Need to address an IDOC for tests for which you cannot spike. Also, does IDOC need to be universal and address all medias?

6. Definitions/Glossary

Changes will be necessary in order to be consistent with Program Policy and Structure Committee proposal. QS Committee will review definitions/glossary at Interim Meeting.

7. Matrix and Medium

A suggestion has been made that the medium definition should in turn be divided into a number of matrices. The committee has pulled into one file all items related to this issue (part of NELAC IV homework).

8. Virginia NELAC Workgroup

Need to develop a definition for the term *client*. The definition should address clients that are internal to an organization as well as external to the organization.

9. Table of Procedures

Review table of procedures prepared by Mr. Frederici for inclusion in Chapter 5.

Attachment D

RESPONSES TO COMMENTS FROM VIRGINIA NELAC WORKGROUP
QUALITY SYSTEMS COMMITTEE
JANUARY 5, 1999

Responses from the QS Committee members are listed below. Responses are listed in order of the section of the QS Chapter to which the comment applied.

1. Joe Slayton
2. David Mendenhall
3. Mary Bruch
4. Ray Frederici
5. Cliff Glowacki
6. Fred Siegelman
7. Sheila Myers

1. RESPONSES FROM JOE SLAYTON

Chapter 5 – Quality Systems

A major concern with the standards as they are written is that they need further development prior to implementation. Additional revisions and clarifications are necessary before laboratories can be expected to meet NELAC requirements. The standards leave room for varying interpretations that will result in inconsistencies. These inconsistencies could occur at any level from the on-site assessment to the interpretation by accrediting authorities. The following are a few of the concerns supporting this position:

Response: one of the basic principles of the QS Committee is to develop standards that are "auditable," i.e., sufficient detail is included so that the accrediting authorities evaluate laboratories consistently and uniformly.

Major Concerns

Several regulatory programs are covered by the NELAC Standards in a "one-size-fits-all" approach. This type of accreditation program just creates another program, in addition to those already in existence, to which laboratories must comply. With this approach, it is heavily implied that these standards were geared toward large commercial laboratories having considerable resources. Smaller commercial, industrial, and municipal laboratories participating in one or two programs are unduly burdened. Although the EPA considers this program voluntary, the NELAC Standards are not voluntary for laboratories operating in states that participate in NELAP. Therefore, EPA and NELAC should be very cognizant of the impact that these standards will have on the laboratory community.

Response: One of the basic principles of the QS committee is to develop standards that are "practical and essential," i.e., the standards represent essential QA policies and QC

procedures and that these standards should not place an unreasonable burden upon the laboratories." The standards are under continued scrutiny and with the input of all stake holders (including the regulated community) the standards are continually improved. The QS chapter not only includes general requirements for environmental laboratories but also requirements specific to fields of testing, e.g., chemistry, microbiology, radiochemistry, etc. The QS standards were developed so as to apply to all environmental laboratories regardless of size or complexity (large and small alike). The approach to accreditation is to a degree patterned after the certification program for drinking water, but the standards were developed based on the guiding principles of the QC committee and the "Conference Process" (for details see QS minutes on the Web).

Furthermore, the economic impact of NELAC implementation has not been fully explored. Although it is voluntary for states to adopt this program, it is not voluntary for laboratories operating in those states adopting the program. Under the current standards, many small and medium sized labs, municipal, industrial, and commercial, will be driven out of business due to increased costs and/or administrative red tape. Large laboratories will reap the immediate windfall: added future benefit of reduced competition, higher prices charged to customers, reduced customer satisfaction, fewer analysts employed, and reduced employment opportunities in the environmental chemistry field. It seems that the economic impact that will occur in some states may boarder on an unfunded mandate. This impact could be devastating to some laboratories. These "side effects" of NELAC do not seem conducive to assuring quality data. Before finalizing standards, the full economic impacts of implementation should be addressed and evaluated. Otherwise, we need to change the name of the program to "National Commercial Environmental Laboratory Accreditation Conference" and recognize it for what it really is.

Response: QS committee does not have data on the economic impact of implementation of NELAC. We think this issue would be more appropriate for the Policy and Structure Committee and we are sure they would welcome any data that VA WE (etc.) could provide.

In an attempt to cover as many programs as possible, the intent of the NELAC Standards has been compromised. It appears the criteria from the Safe Drinking Water Act (SDWA) have been prescribed universally to all programs and matrices. In several instances NELAC Standards conflict with "approved or promulgated" requirements for various programs. For example, a laboratory could be in strict compliance with the NELAC Standards but out of compliance with regulatory requirements. This conflict cannot occur if NELAP wishes to be successful. Which has priority, NELAC or the approved method/regulatory requirement? Even though the method has priority, laboratories will still be trying to comply with method and program QC requirements for a number of programs across various media. The NELAC Standards need to clearly state that program and method requirements have priority over NELAC Standards. Also, if a program or method requirements conflict with a NELAC standard, then a laboratory should not receive an "unsatisfactory" rating for not

following the NELAC Standards. It is impossible to have one set of criteria govern several diverse programs. Instead of the "one-size-fits-all" approach, a tiered system for all sections in the standard would be less onerous for participating laboratories.

Response: The NELAC approach to accreditation is a tiered approach, which includes meeting program requirements. NELAC realizes that there are differences between the requirements of the various EPA regulatory programs and this approach allows for such differences, e.g., a laboratory will be accredited for SDWA and/or RCRA and or NPDES etc. The QS standards in its scope 5.1 requires that more stringent standards must be followed, whether those of QS or of the required analytical method/s.

Large commercial laboratories have developed significant, in-depth systems (including quality systems). Smaller commercial, municipal or industrial laboratories have quality systems in place, but they are usually less formalized and encompassing. Large laboratories will be transitioning their existing systems to comply with NELAC Standards, while small laboratories will have to create and implement many of these systems. Small laboratories have fewer staff members to dedicate to such efforts in addition to their already taxing analytical demands. Therefore, a phased approach to compliance giving small laboratories a more flexible time line (approximately twice as long as large, commercial labs) in which to implement the NELAC standard should be considered.

NELAC needs to consider the fact that laboratories will never have equal or lesser requirements than regulatory programs by following these standards - *only more!* It seems unfair to laboratories to burden them with more requirements than what is required by the regulatory program(s) in which they participate. Does this guarantee data quality and if so, at what cost?

Response: In terms of size, it may well be easier for a small laboratory with relatively simple operations to update its quality system to match that of Chapter 5 than for a large complex laboratory. We agree that it will take the most effort for a laboratory which lacks a quality system or with a system that is not well documented. The tiered approach to accreditation is more an issue for the Policy and Structure Committee.

The NELAC Standards imply that a laboratory is a professional workplace and requires highly trained and technical individuals. However, the overall tone of the program is negative. In many areas, labs are assumed guilty until proven innocent. At all times laboratory staff should be considered professionals in their field and addressed as such.

Response: QS does not agree that the tone of the standards is negative.

Since the inception of a national laboratory accreditation program, the laboratory community has emphasized the need for training. Training efforts to assist laboratories in implementing the program seem to have fallen by the wayside. This is a major

oversight. Demonstration programs should be sponsored by EPA so laboratories will have an opportunity to fully understand all of the issues associated with NELAP.

Response: We suggest that this is more an issue for your State and its implementation of this program than for NELAC.

Simplicity is the key to success. In keeping with EPA's efforts, streamline the standards. The verbosity of the document is often confusing. In many cases, the editorial styles are different and superfluous text is present. Perhaps guidance from a technical editor to standardize styles and streamline the wording would be helpful.

For example, section D.2 is confusing. Several references to "permits" and their requirements are made, however, the remainder of the chapter fails to reference them as a guide for requirements. The chapter should be written more consistently throughout by avoiding the use of "permits." There will be cases where permits are not involved but standards for toxicity testing are required. The standards should be written independently of specific reference documents. Likewise, all references to "manuals" in Section D.2 should be removed for the same reason. It is implied that "manuals" refers to EPA's toxicity test methods, but again there are circumstances where these "manuals" do not apply and standards are necessary. This is true particularly for the West Coast.

Response: 2.1.b. "The standards for the use, type and frequency of testing are specified by the test methods and by permit and shall be followed." The intent was to allow for requirements of a permit. The assumption is that Whole Effluent Toxicity is frequently associated with NPDES permit requirements. Suggested alternate language is always welcome.

Several references are made to "written notification" in the standards. It is not clear if e-mail is considered "written notification." E-mail is often challenged as not being equivalent to actual written correspondence. However e-mail is becoming the default mode of communication between (and within) organizations of all sizes. Electronic deliverables as a whole are becoming more commonplace and need to be addressed as an acceptable means of "notification."

Response: The QS standards do not preclude the use electronic options.

Can the level of documentation required for every minute process be supported by the benefits obtained versus the burden placed on the laboratory if ensuring high data quality is truly the objective of NELAC Standards? Creating this type of paper trail may be a lawyer's nirvana but in reality only another paperwork bureaucracy has been established. Since data quality is the objective, analysts must focus on the analytical benchwork - not filling out forms and other paperwork that account for each minute of the day.

Response: One of the basic principles of the QS committee is to develop standards that are "practical and essential," i.e., the standards represent essential QA policies and QC procedures and that these standards should not place an unreasonable burden upon the laboratories." The standards, including those concerning documentation, are under continued scrutony and with the input of all stake holders (including the regulated community) the standards are continually improved.

Additionally, NELAP should use data quality objectives for the accreditation of environmental labs. As written, it appears that laboratories may gain accreditation based on the ability to fill out forms, not on the ability to produce high quality data. Which is more important? It almost appears that the quality of the data produced is secondary to the ability to successfully complete the paperwork maze. By imposing layer upon layer of administrative activities and systems, operations will eventually collapse under the tremendous bulk. Heavily administered laboratories that produce reams of paperwork can still produce poor quality data.

Chapter 5 is much more prescriptive than the other chapters in the standard. To maintain consistency, the level of detail should be consistent across all of the chapters. For example, the requirements of the Quality Assurance Officer are very prescriptive. Requirements for inspectors are somewhat vague. Requirements for both positions should be described in the same amount of detail. Also, specific requirements for the training and "certification" of in-house auditors and the QC Officer are not addressed. Does NELAC have standards for these training requirements and for the issues and areas to be addressed during in-house audits? More direction and detail would be helpful. Additionally, several key areas that should be very descriptive are vague and open to varied interpretation (e.g. training for the analysts and internal "auditors"). This ambiguity will result in the very thing that the program is trying to avoid - *inconsistency*! Conversely, areas where latitude should be given (e.g. writing down of all formulas and equations including those with complex algorithms internal to the instrument software) should not be mandated but left to the regulatory agency to determine the necessary detail.

Response: Opinions vary with regard to what areas that should be given more latitude. Our goal is to provide essential QC to assure documented quality and yet assure the laboratories have "flexibility" (a basic QS principle: allow laboratories freedom to use their experience and expertise in performing their work and allow for new and novel analytical methods and approaches).

Although the standard is very prescriptive, the contents of required documentation listed in several sections are unclear. An example of each completed document or a table listing each document and the required contents would be helpful.

Response: QS committee has been working on such a table and hopes to include the table as an appendix in future versions of the standards.

Since many organizations follow "total quality" principles (e.g. MTQ, TQM, etc.) the term "client" can have many meanings. The intent of the term "client" used in this standard needs clarification. The standard prescribes actions or procedures that the laboratory must undertake to protect the client or keep the client informed. One example is the need to inform a client in writing if certain tests are subcontracted (Section 5.14.a, Page 39). Is the intent that an internal analytical services laboratory notify, in writing, their sister environmental engineering group of a need to outsource a particular test? As previously stated, it is obvious that this was written with commercial laboratories in mind, not municipal or internal industrial laboratories.

Response: QS committee will explore a definition for "client."

Data quality rests with the bench analysts. The prescriptive nature of the standards and extensive record keeping does not ensure high data quality but acts to preclude the analyst from making necessary decisions which may conflict with the extremely prescriptive standards. By prohibiting analysts from using their best professional judgement on a case by case basis, the very thing NELAC wants to prevent – *poor quality data* – may occur. The analysts should be treated as what they are – professionals!

A more reliable indicator of overall data quality is historical data. By "going outside of the box" and not relying on an 80-page checklist or a ridiculous amount of documentation, the accrediting authority will be tasked with being knowledgeable and having experience in the parameters being evaluated. Is this the underlying reason for the prescriptiveness of the standards?

Response: One of the basic principles of the QS Committee is to develop standards that are "practical and essential," i.e., the standards represent essential QA policies and QC procedures and that these standards should not place an unreasonable burden upon the laboratories." The standards are under continued scrutiny, and with the input of all stake holders (including the regulated community) the standards are continually improved.

Although many requirements are stated, in many cases the true intent of these requirements needs definition. At times the intent appears to be one thing, however, several interpretations could be construed from the same statement. This is especially true in many parts of Section 5.9. This ambiguity may cause inconsistencies and misunderstandings. For NELAC to be successful this type of inconsistency and ambiguity must be abated and the intent clearly stated.

As for Section 5.9, many parts are ambiguous and could have a myriad of interpretations. Please rework the chapter to ensure that the intent is clearly stated. It would help to break that section up into smaller sections dealing with calibration and verification of specific types of support equipment, i.e., a section for balances, thermometers, pipettors, etc. Also, the discussion concerning reference standards for calibration/verification is unclear. Clarification would be greatly appreciated.

Response: QS Committee is proposing an major rewrite of section 5.9

One area that desperately needs measures instituted that aren't currently in place, but have been determined by experts in the field to be important in qualifying test results and increasing data quality, is the area of toxicity testing. Examples of these measures include dose response curves, intra-lab precision, control precision, test sensitivity and statistical power, as well as detection and quantitation limits. EPA has not established quantitative requirements for these parameters in all but a few cases (EPA Region VI and IX, North Carolina, and Washington). Consistency and reliability in toxicity test results, which is the goal of instituting NELAC Standards, cannot be achieved for toxicity testing if these issues are not addressed.

Response: Changing EPA requirements is beyond the scope of NELAC.

Also, the need for simultaneous reference toxicity testing should be considered. Would a chemist use MS and MSD from analyses conducted weeks or months ago to qualify analyses being conducted today? It may be that this is only an issue for tests using shipped organisms, but the question should be addressed.

Response: Perhaps this is an issue for the PT committee or EPA?

Throughout Chapter 5, references to terminology such as MDL, QL, MS, MSD, etc. are made in many sections. This terminology is specific to chemical testing and does not apply to toxicity testing. These sections are not titled as chemical-specific, thereby implying that they apply to all analyses. Differentiation of requirements for chemical and biological toxicity tests is needed.

Response: The general requirements in the narrative of Chapter 5 are to be applied where they can be. Specific requirements. Specific field of testing quality control standards are addressed in the attached appendices, e.g., those for whole effluent toxicity.

For some time NELAC and EPA have stated that they support a performance-based approach. The prescriptive nature of Chapter 5 contradicts this statement. Chapter 5 is very prescriptive and does not hint of any type of performance-based approach. Either NELAC should state that it is not supportive of the performance-based process or change the standards to reflect a more favorable performance-based format by setting data quality objectives and letting the laboratories decided how they will comply.

Response: Chapter 5 includes the EMMC's PBMS checklist which has not yet been adopted by EPA. The QS standards refers to PBMS in sections of the standards, e.g., test methods. The quality control requirements of QS are thought by the committee as a mechanism for providing support to the new (as of yet adopted) method system (PBMS), i.e., as a fenced back yard for an infant. The QS standards will provide structure and support for the new method system (PBMS).

A major concern expressed by the laboratory community is that the program lacks a defined system for dissemination of information. Many large laboratories are cognizant of the impacts of this program, however, most small laboratories are not even aware that NELAP exists! During this initial program implementation, it is imperative that all laboratories have input into the development of the standards.

Response: All the NELAC Standards are posted on the Web. All minutes for the various committees, including the QS committee are also posted.

Also, there is no defined comment period hence there is a great deal of variability from committee to committee. These nebulous comment periods make it imperative that an information dissemination system be established. One suggestion is to have participating states notify all laboratories in their state that may fall under the NELAP umbrella concerning comment period deadlines.

Response: We suggest that this is an important issue and encourage your organization to discuss this topic with the Policy and Structure Committee and/or the NELAC Board of Directors.

The need for each prescribed "essential" quality control element in Appendix D is disputable and may not be appropriate for some regulatory programs. Regulatory program Data Quality Objectives should dictate the quality control elements, not an accreditation program. Project specifications, client's requirements, or the laboratory's QA manual should contain the necessary information concerning those QA/QC elements not defined within the method or program.

Response: One of the basic principles of the QS committee is to develop standards that are "practical and essential," i.e., the standards represent essential QA policies and QC procedures and that these standards should not place an unreasonable burden upon the laboratories." The standards are under continued scrutony and with the input of all stake holders (including the regulated community) the standards are continually improved.

Because the results of PT samples decide the livelihood of laboratories, the NELAC Standards should clearly state that PT providers and their laboratories meet or exceed the standards set forth in Chapter 5.

Response: We encourage you to submit this important comment/idea to the Proficiency Testing Committee.

Parking Lot Items/Issues number 1, 4, 5, 7, 8, and 9 still need to be addressed.

Specific Concerns - VIRGINIA NELAC WORKGROUP

HOME WORK - DAVE MENDENHALL, DECEMBER 3, 1998

Chapter Citation	Current Language	Proposed Language	Comments and/or Questions	QS Committee response
5.4.2.a.	"…have managerial staff with the authority and resources needed to discharge their duties…"		Smaller wastewater laboratories may have to be overseen by staff in adjacent agencies, and may not have managers on-site. Provisions for these situations should be made.	The standard doesn't require that the management staff be on-site. The laboratory must be able to show through measurable outcomes that the "managerial staff" is effectively discharging their duties. The QS committee has decided 1/5/99, that as written this standard is conisistent with ISO. In Addition, Chapter 5 does not require that management be on-site.
5.4.2.b.	"…have processes to ensure that its personnel are free from any commercial, financial and other undue pressures that might affect the quality of their work."	"…have processes in place to ensure that commercial or financial concerns of the laboratory operations do not affect personnel in a manner that might adversely affect the quality of their work."	The way the statement reads now it would imply that the laboratory management have a responsibility to ensure lab personnel are free of **personal** financial and undue pressures. This is not realistic.	The suggested wording is closer but it could be that wages [considered a laboratory financial concern] could impact the quality of work. This would appear to ne very difficult to audit against. The intent is to minimize the potential for conflict of interest. The QS committee decided 1/5/99 to keep the standard as written.
5.4.2.d.1.	"…shall be proportioned such that adequate supervision is ensured and"	Delete Statement	How do you determine adequate supervision?	The standard asks for documentation of how the laboratory will proportion the staff to ensure adequate supervision. What ever is written will suffice. It becomes the laboratory's responsibility to ensure that what they document actually works. It becomes auditable when problems are seen in the QA process.
5.4.2.e.	"…The ratio of supervisory to non-supervisory personnel shall be such as to ensure adequate supervision;"	Delete Statement	The standards addressing supervisory to non-supervisory personnel ratio are ambiguous? What is appropriate? The statement makes its point without adding this ambiguous remark.	It is the laboratory's responsibility to determine the ratio needed for adequate supervision in its own facility. New proposed wording REV9.06 describes the expected outcome: The ratio of supervisory to non-supervisory personnel shall be such as to ensure adequate supervision~~;~~ to ensure close adherence to laboratory procedures and accepted techniques. . It becomes auditable when problems are seen in the QA process.
5.4.2.f.	"The technical director(s) shall certify that personnel with appropriate educational and/or technical background perform all tests for which the laboratory is accredited. Such certification shall be documented."	"The technical director(s) shall document that personnel with appropriate educational and/or technical background background perform all	The technical director does not certify individuals but may document that the individual has the appropriate technical background. Should avoid any reference to certification as it has implications that individuals are	Certification is a document that attests something is true. Used in this standard certify may be a matter of preference. This documentation is required initially with each job assignment and is specific for the work the

Chapter Citation	Current Language	Proposed Language	Comments and/or Questions	QS Committee response
		tests for which the laboratory is accredited."	certifying individuals or processes.	personnel will be doing. The QS committee considered this evaluation of competency and decided on 1/5/99 not to change the standard.
5.4.2.g.2 & g3 **See Mary Bruch's Section**				

RESPONSES FROM MARY BRUCH

(See **Addendum to Comments** at the end of this section of Comments/Responses, which reflect discussions by the QS committee 1/5/99)

Responses to Virginia NELAC Workgroup Comments January 4, 1999

Prepared by Mary K. Bruch

5.4.2g The proposed language is the same as the current language The description of the quality assurance officers responsibility and the requirement for a OAO is essential. The reservation in the current statement is that access must be at the highest level where policy and resource decisions are made, as well as, to the technical director. This phrasing gives flexibility in the organization of the Quality Assurance Unit. The current wording should be retained.

'"Where staffing is limited" was added to increase the flexibility in the standard. The proposed staffing to implement quality assurance in conformity to the standard must apply to many different situations and clearly, if the structure cannot be put in place as described, then staffing is limited and adjustments can and should be made. This phrase should be retained.

5.4.2.g2 The current phrasing for this item reads, "have functions independent from laboratory operations for which they have quality assurance oversight." The oversight function can be delegated as designated to another person in the laboratory or outside of it if the QAO must be directly involved in laboratory testing. The addition of, "when possible," weakens the statement and may encourage lack of QA rather than an adjustment to assign another person. Retain the wording as it is.

5.4.2.g3 The important point of the independence of the QAO is exactly that the technical director and management not interfere in this person's evaluation, and further, that these decisions be reported to management after they are made. This is a very important issue and the wording must be retained as is.

5.4.2.g4 Yes, the QAO must have training and experience in the same manner as analyts do. Documentation should be maintained to illustrate familiarity with qualuty assurnace and NELAC in particular.Records Of training of the QAO should be retained.

The requirement for training and and experience is no different.

QAO is not different from other members of the staff. Retain the current statement.

5.4.2h Retain nominate. More than one option for a replacement in the absence of the technical directors or QAO must be available so that a selection can be appointed to sct in a specific situation.

5.4.2j This requirement for proficiency testing is a QA requirement and should be listed even though another chapter defines the details of the testing.

5.5.1 The interpretation suggested by the commentor is exaggerated. The statement implies that there is flexibility in the structuring of a quality system that fits the laboratory. Many laboratories will have to make adjustments in implementation of the stated requirements to permit conformity to NELAC. Different implementation does not infer that the OA system is less comprehensive for a smaller lab. we might want to look at this wording for possible expansion.

5.5.lc The commentor claim that there repetitiveness with 5.2 in the construction of the quality manual. However, there was a misreading. The management statement of objectives is different from that stated for the laboratory Policies and objectives. Indeed, it may have some similarities, but it is different. I am not sure that there is any way to make the contents of these statements clearer. I would retain the wording as it is.

5.5.ld Part of the responsibility of management is to over-see the implementation of the quality system. The availability of the quality system information to the laboratory personnel is the responsibility of the QAO.

The commitment of management to the separation of the quality system\both in writing the management objectives and in action to implement the system ilks essential. It is important to delineate the responsibilities and objectives of the quality system. I do not recommend any change.

5.5.19 Section 5.5.1 is a general presentation of the objectives and responsibilities of Implementing a quality system. A part of this definition of responsibilities, the maintenance of an up-to-date quality manual by the QAO is stressed. The availability of an up-to-date revised quality manual is integral to the functioning of the quality system. It is essential to discuss responsibilities separated from a description of the quality manual.

5.5.2 The listing of "major organizational units" on the title page is meant to include the units covered in the manual. The definition of major is determined by the specific laboratory, Small sub-sections or parts of a laboratory cannot be listed on the title page. The listing should follow the organizational scheme which is also part of the quality manual. No change is required.

5.5.2a A statement is included on the title page listing the individuals responsible for the lab. The "top" management for the units included in the manual is used. This will vary depending on the size and complexity of the organization. It should be stressed that the commitment of top management is essential in the implementation of a quality system.

5.5.2c The "relationship" between management and other units is delineated most easily in an organizational chart to show managerial responsibility. A separate one for laboratory organization may be required. I suggest adding at the end of the sentence: ... e.g., an organizational chart.

5-5.2e The job description of key staff of the laboratory are included in the manual and reference is made to the location of the Job descriptions of support personnel. Change statement to include: ...staff and reference to the file location of the job descriptions of other staff.

5.5.2i Regardless of the size and complexity or type of work, a review mechanism should be included to ensure that a laboratory can perform the proposed work. This statement is definitely not directed to commercial laboratories.

5.5.2j This statement refers to the procedures in place for calibration and verification, not necessarily the procedures subject to frequent change. I suggest considering removing "test" from "verification test procedures."

5.5.2n This statement requires reference to "verification procedures' used in the specific laboratory described in the manual. This is meant to describe which various procedures listed are used by the laboratory and is not a definition.

Addendum to Comments:

The Quality Systems committee, in a phone conference on 1/5/1999, reviewed possible changes in wording suggested in 5.5.2c, 5.5.2e and 5.5.2i. A decision was made not to change the language in any of these items.

Under 5.5.2c, the Committee elaborated on the need for details of the "relationship" between management and other units. The details of the relationship to the quality system should be added to the Quality Manual in a short narrative discussion.

Under 5.5.2e, the Committee noted a confusion in the comments between the contents of the Quality Manual and reference to other manuals and files.

RESPONSES FROM RAY FREDERICI

Ray Homework (2):
Virginia NELAC Work Group letter 9/30/98 items 5.5.3.1 through 5.7.1

5.5.3.1. "…Such audits shall be carried out by the quality assurance officer or designee(s) who are trained and qualified as auditors…" What are the credential and training requirements to be considered qualified as an internal auditor? Who ensures that these qualifications are met? Are there NELAC Standards to be used for internal auditors? This requirement would require that laboratories hire independent auditors to perform their internal audits. This is extreme and costly.

Response:
The NELAC standard does not prescriptively include criteria for internal auditor training or qualifications. It is the laboratory's responsibility to identify the internal auditor(s) training needs, resources and qualifications. The underlying purpose of internal auditing is to ensure laboratory management is aware of the state of compliance to their own quality policies, procedures and practices defined by their quality program and to encourage continual improvement of their quality system. Internal auditing should not only be about finding non-compliance, but should include looking for ways to be more efficient and productive through better processes which ultimately improves overall quality of data and products produced by the laboratory. Although hiring a consultant to perform internal audits would be acceptable, laboratory management may find it more effective to review, understand, and improve the way they do business using their own staff.

Since the scope and capability of each laboratory holding NELAP accreditation will be quit broad, the internal audit function could differ dramatically from one lab to the next. However, it is reasonable to expect that at least one individual has attended a formal external training course on the fundamentals of performing internal quality system audits. Many of these courses are available through university extension programs and professional training organizations. Also, any additional internal auditors may receive an in-service training provided by the formally trained auditor.

The ultimate effectiveness of a laboratory's internal auditing process, will eventually be determined when the laboratory is audited by the "Accrediting Authority". It is recognized that the NELAC Standards lack of prescriptive language which may provide laboratory management an opportunity to skimp on the internal auditing function. However, the laboratory may risk loosing certification due to non-compliance of their quality program and miss an opportunity to improve operations on their schedule and their identified priorities. Self directed prevention is generally more efficient than imposed corrective action.

5.5.3.2. "…activities to ensure its continuing suitability…" "…activities to ensure its continued suitability…" An ongoing review of quality systems should be adequate. The managerial review should be incorporated into the annual report.

Response:
Language in the standard has been revised by the committee. However, the committee could change "continuing" to "continued", but the meaning remains the same.

5.5.3.4. Entire section. Delete Section Performance audits mentioned in items a, b, and c are specified elsewhere in the document. It's unnecessary to repeat these requirements. The others are examples.

Response:
Section 5.5.3.4 is ISO/IEC Guide 25 language. In addition it distinguishes certain activities as performance audits. Even though these activities are repeated in other sections of the standard, bringing them together under the heading "Performance Audits" adds meaning.

5.5.3.5.a.5. "…specify procedures for management…to review corrective action reports."
An example of a corrective action report would be useful. Each laboratory may have it's own type of corrective action report in mind. This could lead to inconsistency.

Response:
It is the laboratory's responsibility to design/define its corrective action report format. Laboratories should have the necessary flexibility to adopt a corrective action reporting format(s) that fits their quality system and meets the needs of their cleints abnd managment. The NELAC standard should not be prescriptive in this regard and should not designate a specific corrective action report format.

5.5.4. "are further described in Appendix D." Delete section and move essential QC procedures to Appendix D. The QC procedures only need to be described once, either here or in the appendices. Multiple entries for the same item can result in contradictory statements.

Response:
The intent of Section 5.5.4 is to include the essential QC elements that are applicable to any methods performed under NELAC accreditation regardless of which category of testing is being accredited. Additional elements unique to each category (or not applicable to all categories) of testing are then listed in appendix D. This hierarchial approach is intended to distinguish common elements which cross all categories from those elements specific to a category. Any redundancies listed in appendix D could be deleted, unless it is intended to add clarity to the appendix D section.

5.5.4.8.c. "The quality control protocols specified by the laboratory's method manual…"
"The quality control protocols specified by the laboratory's standard operating procedures…"

Response:
To be consistent with ISO/IEC Guide 25 the term methods manual is used. The laboratory's methods manual may be a stand alone document or composed of standard operating procedures. By stating "methods manual", the requirement encompasses standard operating procedures.

5.6.2.a. "Defining the minimal level of qualification, experience and skills necessary for all positions in the laboratory. In addition to education and/or experience, basic laboratory skills such as using a balance, colony counting, aseptic or quantitative techniques shall be considered; "Defining the minimal level of qualification, experience and laboratory skills necessary for all positions in the laboratory." Who determines the "necessary qualifications"? Are job descriptions adequate for the determination of what the minimal qualification and experience levels expected?

Response:
NELAC section 4.1.1 defines the minimum qualifications and experience required of the "Technical Director". The minimum requirements for other positions are defined in 5.6.2 and as defined by laboratory management. Using job descriptions to define qualifications may be used. However, the job description must include NELAC requirements and any other requirement defined by management. (i.e., it depends on how well the job descriptions were written).

5.6.2.c.3. "Analyst training shall be considered up to date if an employee file contains a certification that technical personnel have read, understood and agreed to perform the most recent version of the test method (the approved method or standard operating procedure) and documentation of continued proficiency by at least one of the following once per year:" "Analyst training shall be considered up to date if an employee file contains *documentation* that technical personnel have read, understood and agreed to perform the most recent version of the test method (the approved method or standard operating procedure) and documentation of continued proficiency by at least one of the following once per year:" The technical director does not certify individuals but may document that the individual has the appropriate technical background and training. Should avoid any reference to certification as it has implications that individuals are certifying individuals or processes.

Response:
"Certify" as defined in Webster's dictionary: to declare a thing true, accurate, certain by a formal statement, often in writing; verify; attest. The certification is the documentation retained on file. "Certification" is the term desired for this section, and indeed the technical director is certifying that the information (documentation) is accurate and true. It is the documentation that is certified, not the analyst. This record keeping is not intended as a document an analyst can claim for title or position beyond the laboratory's training documentation records.

5.6.2.c.4.ii. "Another initial demonstration of method performance." "Demonstration of method performance."

Response: This section should be corrected as follows: "Another initial demonstration of capability". Initial demonstration of capability is defined in the glossary, whereas, initial demonstration of method performance refers to appendix E which is still draft at this time. Also, the suggested replacement language "demonstration of method performance" is to vague, but "initial demonstration of capability" is definitive.

5.6.2.d. "Documenting all analytical and operational activities of the laboratory." As written, this statement is a bit vague. Either delete or provide broader explanation.

Response: This statement as written may be broad, but it is not vague. It clearly indicates that "Laboratory management shall be responsible for documenting all analytical and operational activities." For clarification, suggest rewording as follows: "Laboratory management shall be responsible for documenting all analytical and operational activities to demonstrate compliance with the quality system requirements."

5.6.2.f. "Ensuring that all sample acceptance criteria are verified and that samples are logged into the sample tracking system and properly labeled and stored." "Provide adequate analyst training to ensure that sample acceptance criteria are verified and that samples are logged into the sample tracking system, properly labeled and stored." In order to fulfill this statement as written a manager would have to personally oversee the acceptance and logging activity of each sample.

Response:

Agree that this statement is awkward and suggest modifying as follows: "to establish procedures and train personnel to ensure that all sample acceptance criteria are verified and that samples are logged into the sample tracking system and properly labeled and stored."

5.6.3. "Records on the relevant qualifications, training, skills and experience of the technical personnel shall be maintained by the laboratory [see 5.6.2.c.)], including records on demonstrated proficiency for each laboratory test method, such as the criteria outlined in 5.10.2.1. for chemical testing." "Records of relevant qualifications, training, skills and experience of technical personnel, including records on demonstrated proficiency for each laboratory test method (as outlined in the criteria in 5.10.2.1. for chemical testing) shall be maintained by the laboratory [see 5.6.2.c)]."

Response:

Agree that this statement is awkward and recommend modifying as suggested.

5.7.1. Note "It is the laboratory's responsibility to comply with the relevant health and safety requirements. This aspect, however, is outside the scope of the Standard." Delete Section. If not within the scope of this standard, it should not be included.

Response:

This statement is clearly indicated as a "note" so that everyone understands that the NELAC standard does not include health and safety specifications, and to clearly articulate that it is the laboratory's responsibility for this aspect of its operation. It does no harm to keep this statement in the standard.

RESPONSES FROM CLIFF GLOWACKI

COMMENT	RESPONSE	RATIONAL
5.9.4.2.1.c. "Prior to use on each working day, balances, ovens, … shall be checked with NIST traceable references (where possible) in the expected use range."	Replace with: Balances, ovens, refrigerators, freezers, incubators, and water baths shall be checked with NIST traceable references, where available, at a frequency defined by the test method or the laboratory's SOP, whichever is most frequent.	Frequency defined by the laboratory SOP is a business decision. How much risk is the lab willing to accept.
5.9.4.2.1.d. "Mechanical volumetric dispensing devices (except Class A glassware) shall be checked for accuracy on a *monthly* basis."	Mechanical volumetric dispensing devices (except Class A glassware) shall be checked for accuracy at a frequency defined by regulation or the laboratory's SOP, whichever is most frequent.	Same as above
5.9.4.3.a. "This verification standard shall be analyzed with each initial calibration and shall be within 15% of the true value unless the laboratory can demonstrate through historical data that wider limits are applicable."	Deleted by QS	
5.9.4.3.b. "Calibration curves shall be prepared…"	Deleted by QS	
5.9.4.3.b.2. "The minimum number of standards to be used in the initial calibration is dependent on the resulting %RSD:"	Deleted by QS	

5.9.4.3.b.3. "If the resulting curve is non-linear, additional standards shall be used."	Deleted by QS
5.9.4.3.b.4. "The number of standards as determined from the above table and a blank shall be used for the initial calibration of the test method." "	Deleted by QS
5.9.4.3.d. "For results to be reported as quantitative…they must be bracketed by calibration or calibration verification standards. All other results must be reported as having a lower confidence level."	Deleted by QS
5.9.4.4.2.a. "These standards shall be analyzed at a frequency of…" "Unless specified in the analytical method, these standards shall be analyzed at a frequency of…"	Deleted by QS
5.9.4.4.2.b. "To the extent possible, the samples in each interval should be bracketed	Deleted by QS
5.9.4.4.2.b. "…At least one standard *shall* be at a low-level concentration…"	Deleted by QS

RESPONSES FROM FRED SIEGELMAN

Fred Siegelman, Homework, December 3, 1998
Response to Virginia NELAC Workgroup comments.

5.10.5.c. "Detailed records shall be maintained on reagent and standard preparation…" "Detailed records shall be maintained on standard preparation…" How much detail about reagent preparation is required? Most methods provide a "cookbook" approach to making reagents. It is unrealistic to document the specifics of every reagent made each time it is made. Is this type of "busy" work going to ensure quality data or further frustrate the analyst and place an undue burden on the laboratory? Furthermore, where is the laboratory supposed to store these records in addition to the mountain of paperwork already required?

Response:
The text has already been changed with "Detailed records" changed to "records." The items to be maintained in the records are not beyond reasonable detail.

Recommendation:
We have already addressed the comment and no other change is necessary.

5.10.6.a. "Section 8.1 through 8.11 of the…Good Automated Laboratory Practices… shall be adopted." Delete for now and revisit the issue later. Reviewers can easily overlook the single-sentence reference to GALP in the NELAC Standards. However, there is considerable detail when one recognizes that the 2185-GALP, 1995 edition, document and its implementation guidance is over 140 pages. Few laboratories fully comprehend these requirements and what they could mean in terms of systems testing and documentation. GALP adoption should be withheld for now until such time that laboratories are given sufficient information and training on their content. EPA and NELAC should look at a phased implementation of GALP as well as evaluate the financial impact on **all** labs before mandating this requirement.

Response:
The text deals with "all laboratories employing microprocessors and computers" not "all labs". NELAC should define standards for computer use. If a laboratory is going to use computers, they should use them in accordance with an appropriate standard.

Recommendation:
No deletion to the text in chapter 5 is recommended. Section 8.1 through 8.11 do not have any unrealistic requirements. The GALP document refers to LIMS and LIMS raw data. Chapter 5 does need text indicating that these requirements must be met by any laboratory using a computer for "the capture, processing..... or retrieval of test data" and must comply with these sections of GALP whether they have a LIMS system or not. Change text from:

"a) all requirements of this Standard (i.e. Chapter 5) are complied with. Section 8.1 through 8.11 of the EPA Document "2185 - Good Automated Laboratory Practices" (1995), shall be adopted as the standard for all laboratories employing microprocessors and computers.**"**

To:

"a) all requirements of this Standard (i.e. Chapter 5) are complied with. Section 8.1 through 8.11 of the EPA Document "2185 - Good Automated Laboratory Practices" (1995), shall be adopted as the standard for all laboratories employing microprocessors and computers ***and will apply to the laboratories' individual microprocessors and computers as well as to LIMS"***.

5.10.6.b. "…computer software is documented and adequate for use;" "…user's manuals for computer software is available and the software is appropriate for its intended use;" How do you document software? This statement needs clarification and guidance for documentation requirements.

Response:
Adherence to the GALP requirements should take care of this.

Recommendation:
No change to chapter 5 recommended.

5.11.1.a. "The laboratory shall assign a unique identification (ID) code to each sample container…" "The laboratory shall assign a unique identification (ID) code to each sample container, such as a unique number or an identifier that include the sample source, sampling point and sample date…" Make it clear that the ID code does not have to be a number.

Response;
This change asks for more detail than needed in a unique identification code. The request for including the sample source, sampling point and sample date means a text description of the sample which would be an awkward sample identifier. These are items that must be included in the records but not necessarily as part of the identification code. Section 5.11.1 b) does require an unequivocal link with the unique field code. An identification code can include other than numbers. Webster's New Word Dictionary, third college edition, includes among the definitions for code: "a system of symbols used as in secret writing or information processing, in which letters, figures, etc. are arbitrarily given certain meanings."

Recommendation:
No change to existing text.

5.12.2.b. "…shall be retained for a minimum of five years." The section essentially states that **all** records shall be retained for a minimum of five years. Clarification as to when the five years starts and ends is needed. As written, several interpretations can be made. For example, does the five years for SOPs start from the date the SOP was put into use or the date on which the SOP was "retired"? Are training records kept for five years after an employee leaves the company?

Response:

Text of chapter 5 requires retention for a minimum of 5 years. This is retention for 5 years after the generation or last use of a record.

Recommendation:
Text in 5.12.2 b) should be changed from ".....for a minimum of five years." to ".....for a minimum of five years from the date of last usage."

5.12.3.1.n. "Disposal of hazardous samples including the date of sample or subsample disposal and name of the responsible person." Delete Section. What does NELAC define as constituting a hazardous sample? Samples classified as acid waste can be considered "hazardous" but by simply neutralizing the pH it is no longer hazardous. These samples are batched for neutralization. It is unrealistic that each sample for neutralization must be specifically identified and documented. What is the purpose of this much documentation of hazardous waste when there are entire programs that govern this concern? Is this really of benefit in ensuring the data quality? As long as laboratory programs comply with appropriate hazardous waste regulations, how samples are disposed of is no concern of NELAC. The role of NELAC is to judge laboratory performance and quality and to grant laboratory accreditation. Recommend deleting this section.

Response:
More detailed text would be of value.

Recommendation:
Add the following to 5.12.3.1.n. text:

> ***Hazardous samples are those defined by the governmental programs, laws, statutes, rules, and regulations with jurisdiction over the laboratory. The laboratory shall have documented procedures for the disposal of these samples that comply with these programs, laws, statutes, rules, and regulations. Disposal shall be compliant with these programs, laws, statutes, rules, and regulations.***

5.12.3.2.a. "All original raw data, whether hard copy or electronic, …" This item implies that both hard copy and electronic raw data must be maintained, if available. Please clarify that the lab need only maintain a hard copy **or** an electronic copy of the raw data, not both.

Response:
This is a requirement for retention of original raw data. If the laboratory has both hard copy and electronic raw data, whichever came first in time is what should be retained. Alternatively, if the laboratory defines in an SOP that the hard copy is the original, than that is what should be retained while if the SOP defines the electronic copy as the original raw data than that is what should be retained. In any case there must be complete retention of the original raw data so that a laboratory assessor can confirm, reconstruct and recreate the purpose for which the data was used.

Recommendation:

Add text to 5.12.3.2 a): "It is the laboratory's responsibility to define original raw data and to retain original raw data sufficient to permit a reconstruction of all calculations, use and reports for which the original raw data was used. The definition of original raw data must be documented in the laboratory's procedures."

5.12.4. Legal or Evidentiary Custody The term legal is confusing. Please clarify legal as "evidentiary samples." Otherwise, this could be confused as *any* sample analyzed for the fulfillment of regulatory requirements.

Response:
Appendix B has definitions for both chain of custody and legal chain of custody that are very similar and could be confusing.

Recommendation:
We need good definitions for legal and evidentiary. We should also delete the reference to the QAMS glossary and to the other sources of definitions from all of our definitions.
We should delete the definition of legal chain of custody and add definitions to Appendix B for legal or evidentiary. The definitions below are place markers until we can find the most appropriate.

evidentiary: presentable in a legal proceeding.

legal: Able to withstand rigorous legal scientific scrutiny.

5.12.4.3. "Access to all legal samples and subsamples shall be controlled and documented." Please clarify what is considered "legal."

Response:
Please see comments above.

Recommendation:
A better definition of legal should be added to Appendix B.

5.13. "Laboratory Report Format and Contents" Add initial sentence: "The laboratory should report results as specified by its customer or the applicable regulatory program. In cases in which the report format is not defined, the laboratory should report results as defined below." The client or regulatory program should define reporting requirements, not NELAC.

Response:
Clarification could be of value. There are several possibilities for change including:
B: Add change to text as requested.

C: ***The text in 5.1 b) "***If more stringent standards or requirements are included in a mandated test method or by regulation, the laboratory shall demonstrate that such requirements are met. (See the supplemental accreditation requirements in Section 1.9.2.)" ***may already cover this or***

D: ***Change the text in 5.1 b) to: "*** If ***different*** standards or requirements are included in a mandated test method or by regulation, the laboratory shall demonstrate that such requirements are met. (See the supplemental accreditation requirements in Section 1.9.2.)" ***This will significantly change the meaning of the standard.***

Recommendation:
Do A or A and C.

B. *"Quantitation Limits*: …for the purposes of NELAC, is defined as 3.18 times the MDL…" *"Minimum Level:* …for the purposes of NELAC, is defined as 3.18 times the MDL…" This definition by current EPA convention is termed Minimum Level or ML. QL are often levels that are determined by the regulatory authority and are stated in permits.

Response and Recommendation:
We have already changed text and no further change necessary.

B. Laboratory Control Sample "Laboratory Fortified Blank (LFB) Terminology should be in-line with EPA's.

Response:
Appendix B definition now reads.

"Laboratory Control Sample (however named, such as laboratory fortified blank or spiked blank): a sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes from a source independent of the calibration standards or a material containing known and verified amounts of analytes. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system. (NELAC)."

Is this a request to change definition to:

"Laboratory Fortified Blank (however named, such as laboratory control sample or spiked blank): a sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes from a source independent of the calibration standards or a material containing known and verified amounts of analytes. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system. (NELAC)."?

Recommendation:
No change since either is acceptable and has the same information

B. Laboratory Duplicate Laboratory Replicate Some analyses may require more than two replicates.

Response.

Change is appropriate.

Recommendation:
Change definition from:

'Laboratory Duplicate: Aliquots of a sample taken from the same container under laboratory conditions and processed and analyzed independently.***"***

to:

"Laboratory Replicate (however named such as laboratory duplicate): Aliquots of a sample taken from the same container under laboratory conditions and processed and analyzed independently."

C. Title "INITIAL DEMONSTRATION OF CAPABILITY" "INITIAL DEMONSTRATION OF CAPABILITY FOR CHEMICAL TESTING" Appendix C, as written, applies only to chemical analyses. It is not indicated, however, through title or text that it only applies to these types of analyses.

Response;
Comment is correct. However, would the change indicated below obligate us to provide demonstration procedures for whole effluent toxicity, microbiology, radiochemical analysis and air testing also?

Recommendation:
Change title of C.1 from;

C.1 PROCEDURE FOR INITIAL DEMONSTRATION OF CAPABILITY.

to:

C.1 PROCEDURE FOR INITIAL DEMONSTRATION OF CAPABILITY FOR CHEMICAL TESTING.

C.1 "An initial demonstration of method performance *must* be made…" "An initial demonstration of method performance *is recommended*…" Various regulatory programs and promulgated methods have initial demonstration of performance requirements. Instead of imposing yet another requirement, let this issue be determined by the program or the method.

Response:
If the effort is for a program that has initial demonstration requirements than that effort would be done in accordance with 5.1 b) "If more stringent standards or requirements are included in a mandated test method or by regulation, the laboratory shall demonstrate that such requirements are met. (See the supplemental accreditation requirements in Section 1.9.2.)"

Recommendation:
No change to the text.

C-3 of 4 We, the undersigned, CERTIFY that: We, the undersigned, acknowledge that:

Response:

The Standard requires certification not acknowledgment. It may be that the concern of the comment is that the signatures required by the Standard do not include the signature of the person actually doing the Initial Demonstration of Capability.

Recommendation:

Do not change "certify" to"acknowledge." Include and require a signature by the analyst. Change text of Certification Statement to:

We, the undersigned, CERTIFY that:

1. The analyst identified below, using the cited test method, which is in use at this facility for the analyses of samples under the National Environmental Laboratory Accreditation Program, have met the Initial Demonstration of Capability.

2. The test method was performed by the analyst(s) identified on this certification.

3. A copy of the test method and the laboratory-specific SOPs are available for all personnel on-site.

4. The data associated with the initial demonstration capability are true, accurate, complete and self-explanatory (1).

5. All raw data (including a copy of this certification form) necessary to reconstruct and validate these analyses have been retained at the facility, and that the associated information is well organized and available for review by authorized inspectors.

_____	_____	_____
Analyst's Name and Title	Signature	Date
_____	_____	_____
Technical Director's Name and Title	Signature	Date
_____	_____	_____
Quality Assurance Officer's Name	Signature	Date

RESPONSES FROM SHEILA MYERS

Virginia NELAC WORKGROUP

NELAC Quality Systems Chapter Comments
C:\DATA\NELAC\MINUTES\QS990105.wpd

Comment:
D.1.1.a.1.i, change, "the blank contamination exceeds a concentration greater than 1/10 of the measured concentration of any sample in the associated sample batch...," to,

Rationale for Comment:
This statement implies that "any sample" would also include field blanks (or other types of blanks) in the evaluation of the measured concentration. Non-detectable concentrations of the analyte would be expected in field blanks. Also, many methods now specify the acceptance criteria for blanks. The NELAC Standards should allow the use of the criteria specified in the methods and guidance documents. If methods do not contain these criteria, then adopt the 1/10 sample concentration approach.

QS Response:
It is the consensus of the Q.S. committee that this section in the standard is essential and therefore is established as minimum. If methods specify the acceptance criteria for blanks that have more stringent criteria, then the more stringent standard applies (as is the case with the entire chapter). We agree that as written, interpretation could be made that a sample may be a field blank and that under this section if a laboratory blank detects 1/10 of a suspect compound of a field blank, all samples would be suspect when in reality the field blank may be of significant magnitudes below any regulatory or otherwise value.

Recommendation
I propose their rewrite of, "the blank contamination exceeds the concentration in the method or is greater than 1/10 of the measured concentration of any non-blank sample in the associated sample batch...," be adopted.
Or rewrite of the section to distinguish samples from field quality control samples (such as blanks). Or provide a definition of sample to distinguish between quality control field samples. This however may cause problems elsewhere in the chapter.

Comment:
D.1.1a.1.I, change, "the blank contamination exceeds the concentration present in the sample and is greater than 1/10 of the specified regulatory limit.", to "... the blank contamination exceeds the concentration present in the samples, is greater than 1/10 of the specified regulatory limit, or criteria found in individual analytical methods."

Rationale for Comment:
Current guidance in most proposed EPA "clean" methods allow for blank contamination up to 1/3 of the regulatory limit. For clean, ultra clean, and methods requiring a pre-concentration step, the criterion of 1/10 of the specified regulatory limit is not sufficient. Perhaps different

acceptance criteria need to be developed for these types of unique situations or allow use of the criteria specified in the methods and guidance documents.

QS Response:
Individual analytical methods requirements do not take precedent unless they are more stringent. This standard is considered an essential and minimum requirement. QS committee believes that dependent upon needs, programs will develop criteria depending upon data use. Until then, as stated before this has been determined to be essential minimum QC.

Recommendation:
No changes to standard.

Comment:
D.1.4.c., change, "All quantitatively reported results...shall be bracketed by calibration or calibration verification standards.", to "All reported results...shall be bracketed by calibration or calibration verification standards."

Rationale for Comment:
As stated earlier, any results that may be questioned in court must be bracketed by valid CCVs to be considered valid.

QS Response:
QS committee suggest that you become very familiar with the entire standard regarding quantitatively vs. non-quantitative data. In the standards, only data bracketed by calibration or calibration verification standards may be reported out. Data not bracketed by calibration standards will be qualified, or could be reported out as a greater than number. An example would be exceeding a regulatory limit by 10 or 100. Exceeded of the limit is of consequence but not necessarily whether it is by 10, 100 or 1000. Again, this has limited application, but was strongly argued for by the RCRA program. It gives laboratories and programs additional flexibility.

Recommendation:
No changes to standard.

Comment:
D.1.7.b., change, "A confirmation shall be performed to verify the compound identification when positive results are detected on a sample from a location that has not been previously tested by the laboratory." to, " It is recommended to perform confirmation for a compound to verify the compound identification when positive results are detected on a sample from a location that has not been previously tested by the laboratory."

Rationale for Comment:
Historical data generated by another laboratory may be available. Confirmation for compounds found in sample should be left to method/regulatory specification, the discretion of the analyst or prior request of the client.

QS Response:
QS disagrees with this rationale. This standard is considered essential and practical and therefore will not be put in as a recommendation**.** We strongly disagree that confirmation of compounds found in a sample should be left to the analyst or request of the client. A confirmation shall be performed at a minimum when positive results are detected on a sample from location that has not been previously tested by the laboratory.

Recommendation
No changes to standard.

Comment:
D,1,7,b., change, "Confirmation is required unless stipulated in writing by the client.", to "Confirmation is recommended unless stipulated by the client."

Rationale for Comment:
It is not always possible to contact the client in a timely manner. Again, confirmation for compounds found in sample should be left to methods/regulatory specifications, the discretion of the analyst or the prior request of the client.

QS Response:
It is of the opinion of the QS committee that confirmation is an essential minimum quality assurance requirement. If methods or regulatory requirements are more stringent, then they will apply. Refer also to above response.

Recommendation:
No changes to standard.

Comment:
"D.1.7.c., Delete, "The laboratory shall develop and document acceptance criteria for mass spectral tuning."

Rationale for Comment:
These criteria are usually stated in the method.

QS Response: I agree that this sentence is lacking direction. Documentation is understandable but "develop" needs to be clarified, or the entire sentence should be deleted. I agree with the comment, all GC/MS tuning criteria I am aware of is specified in the methods.

Recommendation:
I propose that a change be made to, "The laboratory shall develop (if not specified by method, or using a PBMS method) and document acceptance criteria for mass spectral tuning." For people who are very familiar with the standard, this goes without saying anyway. But I think it should be added to the standard for clarification. Second choice is to delete D.1.7.c as per the comment **(Committee discussion).**

Comment:
D2.1.a.1.1, change “whole effluent toxicity” to “toxicity.

Rationale for Comment:
These standards may apply to all types of toxicity testing other than for effluent (e.g. storm water, ambient water, etc.)

QS Response: I agree, but would always include whole effluent toxicity as an example.

Recommendation:
Make change as stated in comment, (Mary does this sound acceptable)?

Comment:
D2.1.a.1.1 “The laboratory must demonstrate its ability to obtain consistent results...” **No suggested change was given**.

QS Response:
No comment

Recommendation:
No change to standard

Comment:
D.2.1.a.1.i, change, “An intra laboratory coefficient of variation (%CV) is not established for each test method...”, to, “An intra laboratory coefficient of variation (%CV) is established for each test method...”

Rationale for Comment:
C’S are specific to each test method, each toxicant, test duration, temperature, dilution water and biological endpoint. All of these parameters can vary within a test method.

QS Response: Discuss with Mary Bruch on the committee. I’m not sure I understand the first sentence in D.2.1.a.1.i. either.

Comment:
D.2.1.a.1.i, states, “...a testing laboratory shall maintain control charts for the control performance and reference toxicant statistical endpoint...” A description of the type of control chart is needed. There are different types of control charts: one type plots performance changes with time: another is used to gage acceptability of a batch of organisms by the sensitivities of previously tested batches. Please specify to which type the text is referring. Also, please explain the difference between a control chart and the quality control chart referenced in D2..1.a.1.ii. Definition have not been provided.

QS Response: (1) As stated in the comment, there are different types of control charts, for this reason it is undesirable to select specific control charts needed. **These standards specify the “what” and avoid where possible the “how to”.** This allows laboratories freedom to use

their experience/expertise and pave the path for Performance Based Measurement System approaches. **(2)**There seems to be no apparent difference between “control charts” and “quality control charts”. As all control charts in the standard could be referred to as “quality control charts”.

Recommendation: (1) No change to the standard. (2) Change document to all “quality control charts”, or “control charts”.

Comment:
D.2.1.1.i, states “...shall maintain control charts for the control performance and reference toxicant statistical endpoint (such as NOEC or Ecp)...” Sub-section (I) states that control charts are established for hypothesis test endpoints such a NOEC, however section (ii) only references point estimates. Please explain this inconsistency. Additionally, the text should describe how a control chart is designed for hypothesis test endpoints and how intra-lab variability is expressed for hypothesis test endpoints. These types of endpoints can not be averaged because they are a function of the dilution scheme used in the test. Different dilution schemes will result in different quantities of precision. Intra-lab performance standards for hypothesis test endpoints can not be established unless these standards establish mandatory dilution schemes.

QS Response: Comment will be directed to Mary Bruch to evaluate.